



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/767,244	01/27/2004	Gary W. King	11738.00215	4773

22908 7590 03/13/2006

BANNER & WITCOFF, LTD.
TEN SOUTH WACKER DRIVE
SUITE 3000
CHICAGO, IL 60606

EXAMINER

EVANISKO, GEORGE ROBERT

ART UNIT	PAPER NUMBER
----------	--------------

3762

DATE MAILED: 03/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/767,244

Applicant(s)

KING ET AL.

Examiner

George R. Evanisko

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-43 is/are pending in the application.
- 4a) Of the above claim(s) 13-43 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>3/3/05</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Claims 13-31 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention and species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 12/16/05.

Newly submitted claims 32-43 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claims 32-43 are a combination of the originally presented subcombination claims. New claims 32-43 and original claims 1-12 are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the combination does not require therapy elements or the extendable member connected to first and second points. The subcombination has separate utility such as a medical device not requiring an actuator but using heat activated metals to expand the extendable member.

Since applicant has elected the invention of group I in the reply of 12/16/05, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 32-43 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, lines 6 and 7 use the terms “compact position” and “extended position” and line 14 uses the term “compact” but lines 14, 18, and 19 use the term “expand”, “contract” and “expand”. It is unclear if the compact and extended positions are the same as contract and expand. It is suggested to use the same terms to define the compact and extended positions of the elongated member.

In claim 2, “a first strut and second strut” and “ a third strut and a fourth strut” are inferentially included and it is unclear if the applicant is positively reciting these elements. It is suggested to first recite the elements before they are used in the claim. In addition, it is unclear if these are the same struts used in claim 1 or different struts.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-9, 11, and 12 are rejected under 35 U.S.C. 102(e) as being anticipated by Avitall (5702438). Avitall shows in figures 4-6 the extendable span member as elements 32 and 34, having connecting elements/struts, 38a, 38b, and the two struts directly opposite 38a and 38b on the other side of the midline of the lead, with the struts connected to a first point/link (where reference number 34 is pointing between the electrodes) and a second point/link (directly opposite the first point, on spine 32). It is noted that struts 38a and 38b are pivotally linked to one another at the first point/link (reference number 34) through the spine member 34 (and the other struts are linked at the second point/link through spine member 32) and that the claims do not state that the struts are directly connected to each other. Also, the first/second point is considered to be the first/second link since the struts are linked/connected together at these points and/or connected through the top parts of spines 34 and 32. It is noted that sheath 18 can be withdrawn and or other catheters can be sequentially employed (column 6, lines 60-65) and that the sheath(s) functions as the locking mechanism compressed over the struts/links since the struts/links are restricted by the sheath and since the sheath does not allow the struts to extend. In addition, a control element or wire is used to expand the lead (column 6, line 43, column 7, lines 25-28 and figures 4-6). For claim 11, the span "folds" (i.e. from an extended position to a closed position) when the extendable member expand and contract.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 10 is rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Avitall. Avitall shows the tether at element 38c and corresponding element directly opposite of element 38c.

In the alternative, Avitall discloses the claimed invention except for the tether between the first and second points. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the lead as taught by Avitall, with the tether between the first and second points since it was known in the art that extendable leads use a tether between points to limit how much the extendable member can expand so that the lead maintains its proper shape and/or does not damage tissue.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference

Art Unit: 3762

claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-12 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-16, claims 1-19, claims 1-21, and claims 27-32, 73, and 77 of U.S. Patent Nos. 6714822, 6442435, 6161047, and 6795737, respectively.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented claims are more narrow and meet the limitations of this application's claims. In addition, it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the patented claims a linkage assembly with struts connected at first and second points/links for the extendable member to be connected to the first and second points, to use a removable sheath to function as a lock, and to use a tether since it was known in the art that extendable leads use: a linkage assembly with struts connected at first and second points/links for the extendable member to be connected to the first and second points to allow the extendable member to expand when needed for therapy and contract when not needed; to use a removable sheath to function as a lock to prevent the extendable member from expanding when not needed; and to use a tether to keep the proper shape of the extendable member.

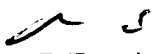
Art Unit: 3762

Any inquiry concerning this communication or earlier communications from the examiner should be directed to George R. Evanisko whose telephone number is 571 272 4945.

The examiner can normally be reached on M-F 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571 272 4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


George R Evanisko
Primary Examiner
Art Unit 3762

3/3/6

GRE
March 3, 2006